

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BAUSCH & LOMB INCORPORATED,
Petitioner,

v.

ZEAVISION, LLC,
Patent Owner.

IPR2022-00089
Patent 10,307,384 B2

Before ZHENYU YANG, TINA E. HULSE, and ROBERT A. POLLOCK,
Administrative Patent Judges.

HULSE, *Administrative Patent Judge.*

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314, 37 C.F.R. § 42.4

I. INTRODUCTION

Bausch & Lomb Incorporated (“Petitioner”) filed a Petition requesting an *inter partes* review of claims 12–14, 16–21, 23, and 24 of U.S. Patent No. 10,307,384 B2 (Ex. 1001, “the ’384 patent”). Paper 2 (“Pet.”). ZeaVision, LLC (“Patent Owner”) filed a Preliminary Response to the Petition. Paper 6 (“Prelim. Resp.”).

We have authority under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted “unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a). Upon considering the argument and evidence presented in the papers, we determine that Petitioner has established a reasonable likelihood that it would prevail in showing the unpatentability of the claim challenged in the Petition. Accordingly, we institute an *inter partes* review of claims 12–14, 16–21, 23, and 24 of the ’384 patent.

A. *Real Parties-in-Interest*

Petitioner identifies itself as the real party-in-interest. Pet. 3. Patent Owner identifies itself as the real party-in-interest. Paper 4, 2.

B. *Related Proceedings*

The parties state that the ’384 patent has been asserted against Petitioner in a pending case before the U.S. District Court for the Eastern District of Missouri: *ZeaVision, LLC v. Bausch & Lomb Inc.*, No. 4:21-cv-00739 (E.D. Mo). Pet. 4; Paper 4, 2.

C. *The ’384 Patent*

The ’384 patent “relates to orally-ingested formulations for treating or preventing eye diseases and vision problems.” Ex. 1001, 1:22–24. The ’384 patent explains that carotenoids are important because they can absorb

ultraviolet (“UV”) and blue light. *Id.* at 4:25–33. Carotenoids are effective anti-oxidants that neutralize oxygen free radicals that result from UV radiation damage. *Id.* at 5:3–27. Carotenoids, however, cannot be synthesized by humans, who must therefore obtain carotenoids in food or dietary supplements. *Id.* at 4:33–35.

Zeaxanthin and lutein are the only two carotenoids found in the macula, which is the center of the retina. *Id.* at 6:27–31. The macula is responsible for fine resolution and must therefore be healthy for good vision. *Id.* at 9:16–18. The macula deposits the highest concentration of zeaxanthin in the center, most crucial part of the macula and deposits lutein in a ring around the zeaxanthin. *Id.* at 9:46–10:3. Macular degeneration is the leading cause of blindness among the elderly. *Id.* at 9:24–25. Studies have shown that people with below-normal concentrations of zeaxanthin in their macula have higher risks and rates of macular degeneration than those with normal levels. *Id.* at 9:45–49.

As described in the ’384 patent, “human retinas have developed and evolved with a notable and substantial preference for zeaxanthin, over lutein.” *Id.* at 10:31–33. Zeaxanthin, however, is scarce in dietary sources, whereas lutein is relatively abundant. *Id.* at 10:12–13. The ’384 specification states that the only isomer of zeaxanthin that is present in dietary sources is the 3R, 3'R stereoisomer (or R—R isomer). *Id.* at 10:30–52. Although the human retina can convert lutein into zeaxanthin, it cannot convert lutein into the same isomer of zeaxanthin that is present in the natural diet. *Id.* at 10:36–40. Rather, the retina can only convert lutein into the S—R stereoisomer, or meso-zeaxanthin, which has not been shown to exist in any known dietary sources. *Id.* at 10:48–55.

Accordingly, it is an object of the invention to disclose oral formulations for mammals that “contain zeaxanthin as an essential and critical ingredient, and which also contain at least two or more other agents that have been proven . . . to act in a synergistic and potentiating manner with zeaxanthin, to provide improved efficacy in preventing or treating eye diseases.” *Id.* at 15:45–53.

D. Illustrative Claim

Petitioner challenges claims 12–14, 16–21, 23, and 24 of the ’384 patent. Claim 12, the only independent claim challenged, is representative and is reproduced below.

12. A nutrient formulation for oral ingestion for protecting a user’s eyes from the harmful effect of blue light, the formulation comprising:

- a. zeaxanthin that is present in the 3R-3R' stereoisomer form and is substantially free of meso-zeaxanthin stereoisomers;
- b. lutein;
- c. vitamin C; and
- d. mixed tocopherols;

wherein the nutrient formulation is provided in the form selected from the group consisting of capsules, tablets, liquids, and powders for oral ingestion.

Ex. 1001, 37:13–25.

Dependent claims 13, 14, 18–20, 23, and 24 recite additional components of the nutrient formulation; dependent claim 16 recites a specific dosage of zeaxanthin; dependent claim 17 recites a specific dosage form for the formulation; and dependent claim 21 recites specific eye disorders of the user of the formulation. *Id.* at 37:26–38:27.

E. The Asserted Grounds of Unpatentability

Petitioner asserts that claims 12–14, 16–21, 23, and 24 are unpatentable on the following grounds:

Claims Challenged	35 U.S.C. § ¹	Reference(s)/Basis
12, 13, 17–21, 23, 24	102(b)	Lang ²
12, 17, 18, 20	102(a), (e)	Barker ³
12, 13, 16–21, 23, 24	103(a)	Lang, Garnett ⁴
14	103(a)	Lang, Garnett, Brown ^{5, 6}
12, 13, 17–21, 23, 24	103(a)	Lang, Roche ⁷
14	103(a)	Lang, Roche, Brown

Petitioner also relies on the Declaration of Dr. Elizabeth J. Johnson.
Ex. 1024. Patent Owner relies on the Declaration of Dr. C. Kathleen Dorey.
Ex. 2001.

¹ Because the claims at issue have an effective filing date before March 16, 2013, the effective date of the applicable provisions of the Leahy Smith America Invents Act, Pub. L. No. 112–29, 125 Stat. 284 (2011) (“AIA”), we apply the pre-AIA versions of 35 U.S.C. §§ 102 and 103(a) in this Decision.

² WO 01/19383 A1, published Mar. 22, 2001 (Ex. 1009).

³ WO 03/063848 A1, published Aug. 7, 2003 (Ex. 1011).

⁴ Garnett et al., US 5,747,544, issued May 5, 1998 (Ex. 1012)

⁵ Brown et al., *Nutrition Supplements and the Eye*, 12 EYE 127–33 (1998) (Ex. 1014).

⁶ Although Petitioner groups Brown together with Lang and Garnett and Lang and Roche in Grounds 3 and 4, respectively, Petitioner only relies on Brown for claim 14. *See* Pet. 6, 56, 72–73. We have therefore separated claim 14 from the other claims that only rely on the combination of Lang and Garnett and of Lang and Roche.

⁷ FDA Docket No. 95S-0316, 75-Day Premarket Notification for New Dietary Ingredient Zeaxanthin by Roche Vitamins, Inc. (opened for public inspection June 2001) (Ex. 1020).

II. ANALYSIS

A. *Person of Ordinary Skill in the Art*

Petitioner asserts that a person of ordinary skill in the art at the time of the invention would have had:

a Masters or a Ph.D. degree in nutritional science, chemistry, biology, biochemistry, or a related discipline or an M.D. or doctor of optometry (“O.D.”), and a few years of practical experience in the nutritional supplement area, including an understanding of formulations that could be considered for promoting eye health, including preventing or treating eye disorders such as macular degeneration. Alternatively, such a person could have been a person with a Bachelor’s degree with a greater number of years of experience. The POSITA would have, or would have access to, general information regarding eye health and eye disorders, the convenience and needs of patients who suffer from eye disorders such as macular degeneration, and background information. And to the extent needed, the POSITA would have collaborated with others having ordinary skill in the areas pertinent to the subject matter of the ’384 Patent.

Pet. 7–8 (citing Ex. 1024 ¶ 16).

Patent Owner states that “[f]or purposes of this Preliminary Response, Patent Owner does not contest [Petitioner’s] definition.” Prelim. Resp. 11.

We adopt Petitioner’s definition as it appears to be consistent with the prior art’s demonstration of the level of ordinary skill in the art at the time of the invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required “where the prior art itself reflects an appropriate level and a need for testimony is not shown” (*quoting Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985))).

Moreover, we find on this record that Dr. Johnson and Dr. Dorey are both qualified to opine from the perspective of a skilled artisan as both are

persons of at least ordinary skill in the art. *See* Ex. 1024 ¶¶ 2–11, App’x A; Ex. 2001 ¶¶ 4–14, App’x A.

B. Claim Construction

In an *inter partes* review, the Board applies the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b). 37 C.F.R. § 100(b) (2021). Under that standard, claim terms “are generally given their ordinary and customary meaning” as understood by a person of ordinary skill in the art at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc). “In determining the meaning of the disputed claim limitation, we look principally to the intrinsic evidence of record, examining the claim language itself, the written description, and the prosecution history, if in evidence.” *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1014 (Fed. Cir. 2006) (citing *Phillips*, 415 F.3d at 1312–17). Extrinsic evidence is “less significant than the intrinsic record in determining ‘the legally operative meaning of claim language.’” *Phillips*, 415 F.3d at 1317.

1. Preamble

Petitioner contends the preamble of claim 12 is limiting. Pet. 16. Petitioner asserts that the preamble provides antecedent basis for the term “the nutrient formulation” recited in the body of the claim. *Id.* Moreover, Petitioner asserts the specification repeatedly describes the use of the formulation to protect the eyes against damage from UV and blue light. *Id.* at 16–17. Petitioner also argues that Patent Owner amended the claims to recite the preamble language in response to prior art rejections. *Id.* at 17. Thus, according to Petitioner, a person of ordinary skill in the art would have understood the preamble of the claim to limit the scope of the claim.

Patent Owner contends the preamble of claim 12 is not limiting. Prelim. Resp. 7–8. Patent Owner asserts the body of the claim describes a structurally complete invention without the need for the preamble, and that protecting the user’s eyes from the harmful effects of blue light is merely an intended purpose of the claimed invention, rather than a limitation. *Id.* at 9–10.

On this record, we find the preamble to be limiting. “In general, a preamble limits the invention if it recites essential structure or steps, or if it is necessary to give life, meaning, and vitality to the claim.” *Catalina Mktg. Int’l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002) (quotation omitted). On the other hand, a preamble is not limiting “where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention.” *Id.* Although not dispositive, “dependence on a particular disputed preamble phrase for antecedent basis may limit claim scope because it indicates a reliance on both the preamble and claim body to define the claimed invention.” *See Shoes by Firebug LLC v. Stride Rite Children’s Group, LLC*, 962 F.3d 1362, 1367 (Fed. Cir. 2020) (citation omitted).

Here, the preamble of claim 12 recites: “A nutrient formulation for oral ingestion for protecting a user’s eyes from the harmful effect of blue light, the formulation comprising:.” Ex. 1001, 37:13–15. The body of claim 12 recites “wherein *the* nutrient formulation is provided in the form selected from the group consisting of capsules, tablets, liquids, and powders for oral ingestion.” Ex. 1001, 37:22–24 (emphasis added). Because the first use of “nutrient formulation” is in the preamble, claim 12 relies on the preamble for antecedent basis for “*the* nutrient formulation.” *Id.* (emphasis added). Similarly, claim 22, which depends from claim 12, relies on the preamble of

claim 12 for antecedent basis for the limitation “wherein *the* user has macular degeneration and a lens-related disorder.” *Id.* at 38:21 (emphasis added).

We agree with Petitioner that the specification consistently states that the benefits of carotenoids, such as zeaxanthin and lutein, include the ability to absorb UV and blue light. *See, e.g., id.* at 4:25–31, 5:26–30, 5:51–53. We do not agree, however, that Patent Owner relied on the preamble to overcome a prior art rejection during prosecution. *See* Pet. 17–18. After Patent Owner added claim 12, the examiner allowed the claims. In the Notice of Allowance, the examiner stated: “Applicant by adding secondary ingredients, such as tocopherol and vitamin C has overcome the 101 rejection. Furthermore, the arguments that the prior art does not teach 3R-3R' zeaxanthin being substantially free of meso-zeaxanthin stereoisomers are considered to be persuasive in terms of obviousness rejection.” Ex. 1002, 131. Thus, contrary to Petitioner’s assertion, Patent Owner overcame the rejection by adding the limitation that the 3R-3R' zeaxanthin is substantially free of meso-zeaxanthin stereoisomers, and not because of the preamble reciting protecting the user’s eyes from the harmful effects of blue light. *See id.*

Although a close case, on this record, we determine that the specification and the claim language support construing the preamble as a substantive limitation. We invite the parties to brief this issue further during trial, however, if it continues to be a disputed issue relevant to the outcome of this proceeding.

2. *Remaining Claim Terms*

Petitioner contends the term “substantially-free of meso-zeaxanthin stereoisomers” should have its plain and ordinary meaning, and a person of

ordinary skill in the art would understand this term to mean that the zeaxanthin that is present in the 3R-3R' stereoisomer form is “largely but not wholly free of meso-zeaxanthin stereoisomers.” Pet. 19 (citing Ex. 1024 ¶ 57, Ex. 1031, 3). Patent Owner does not offer a construction for this term. *See generally* Prelim. Resp.

Petitioner also contends the term “mixed tocopherols” should be construed to mean “a mixture of tocopherols such as alpha-, beta-, gamma-, and delta-tocopherols.” Pet. 22–24 (citing Ex. 1024 ¶¶ 65–66). Patent Owner does not offer a construction for this term. *See generally* Prelim. Resp.

Because there does not appear to be any dispute over the construction of these terms, we adopt Petitioner’s proposed constructions as consistent with the plain and ordinary meaning of the terms. *See Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) (“[C]laim terms need only be construed ‘to the extent necessary to resolve the controversy.’” (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

C. Alleged Anticipation Over Lang

Petitioner asserts that claims 12, 13, 17–21, 23, and 24 are unpatentable as anticipated by Lang. Pet. 24–40. Patent Owner opposes Petitioner’s assertion. Prelim. Resp. 12–17. On this record, we determine that Petitioner has established a reasonable likelihood that it would prevail in showing claims 12, 13, 17–20, 23, and 24 are anticipated by Lang, but not claim 21.

1. Lang (Ex. 1009)

Lang relates to beadlet formulations for including in dietary supplements comprising “one or more xanthophylls; one or more carotenes,

retinoids, or combinations thereof; one or more antioxidants; and excipients.” Ex. 1009, 4:7–10. Lang discloses that the dietary supplements are used for “the enhancement of ocular health and the prophylaxis of retinal disorders, including age-related macular degeneration.” *Id.* at 4:17–18.

Lang further states that examples of xanthophylls include lutein and zeaxanthin. *Id.* at 8:7–9. Lang states that “[i]t has been suggested that the particular xanthophylls, zeaxanthin and its isomer lutein, may be beneficial in improving the health of the macula and the clarity of the lens.” *Id.* at 2:17–19. Lang teaches that xanthophylls may be obtained from various dietary sources, such as corn and leafy green vegetables. *Id.* at 8:3–4. Lang also teaches that examples of natural antioxidants and related derivatives include alpha-, beta-, gamma-, delta- and epsilon-tocopherol, as well as Vitamin C. *Id.* at 9:23–10:2.

An example of a beadlet composition is shown in Example 3, reproduced below:

Example 3

Ingredient	Amount (% w/w)
Beta Carotene (natural)	3
Lutein	1.5
Zeaxanthin	1.5
Hydrolyzed Gelatin	30
Vegetable Oil/Oleoresin	23
Sucrose	14.6
Food Grade Corn Starch	17
Ascorbyl Palmitate	2.7
Tocopherol(s)	1.7
Water	5

Example 3 shows a beadlet composition including lutein, zeaxanthin, and tocopherol(s). *Id.* at 12:19. Lang also provides examples of dietary supplement gelatin capsules that incorporate beadlets, such as that of Example 3, along with other nutrients such as Vitamin E to treat various ocular diseases. *See, e.g., id.* at 23:1–8 (Example 12).

2. Analysis

Anticipation requires that “each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (citation omitted). “To establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.’” *Id.* (citation omitted). Moreover, to anticipate, a prior art reference must “disclose[] within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim.” *Net MoneyIN, Inc. v. Verisign, Inc.*, 545 F.3d 1359, 1371 (Fed. Cir. 2008).

Petitioner asserts that Lang discloses each limitation of claim 12. Pet. 28–33. Petitioner asserts that Lang discloses the preamble because it teaches the use of dietary supplements that include lutein and zeaxanthin, which are known to absorb photoexcitative radiation of short visible wavelength that can damage the eyes. *Id.* at 28 (citing Ex. 1009, 2:16–3:6). Petitioner also asserts that Lang discloses the 3R-3R' form of zeaxanthin and is substantially free of meso-zeaxanthin because Lang teaches obtaining zeaxanthin from corn, and a person of ordinary skill in the art would understand that the 3R-3R' stereoisomer is the only zeaxanthin present in dietary sources. *Id.* at 29–30 (citing Ex. 1009, 8:3–7; Ex. 1024 ¶ 84;

Ex. 1001, 10:40–43 (stating “[t]he only isomer of zeaxanthin that is present in dietary sources is the 3R, 3'R stereoisomer”). Finally, Petitioner asserts that Example 12 of Lang, which incorporates Example 3 (referred to by Petitioner as “Lang 12-3”), discloses lutein, vitamin C, and mixed tocopherols in the form of gelatin capsules for oral ingestion. Pet. 31–33 (Ex. 1009, Example 12; Ex. 1024 ¶¶ 87–91).

Patent Owner argues that Lang does not disclose “mixed tocopherols,” as required by claim 12. Prelim. Resp. 13–15. Patent Owner argues that “[a]lthough Lang describes tocopherol(s) in beadlets and vitamin E among the additional nutrients of the dietary supplement, it fails to disclose combining a mixture of two or more tocopherols in one supplement as taught by the '384 Patent.” *Id.* at 13. Patent Owner asserts that a person of ordinary skill in the art would not have understood Lang to require mixed tocopherols because “the benefit of multiple tocopherols in the same supplement was not yet clear in the art.” *Id.* (citing Ex. 2001 ¶ 27).

At this stage of the proceeding, we find Petitioner has shown sufficiently that Lang discloses mixed tocopherols. Example 3 of Lang discloses “tocopherol(s)” as an ingredient of the beadlet, indicating the formulation encompasses a plurality of tocopherols. *See* Ex. 1009, 14. Moreover, Example 12, which incorporates the beadlet of Example 3, discloses Vitamin E among “Other nutrients” in addition to the composition of the beadlet. *Id.* at 23. Thus, at a minimum, Lang 12-3 teaches a formulation that includes tocopherols and Vitamin E.

The parties dispute what isoforms a person of ordinary skill in the art would understand Vitamin E to include. Petitioner’s expert asserts Vitamin E was known to encompass alpha-, beta-, gamma-, and delta- tocopherols. Ex. 1024 ¶ 90. Patent Owner’s expert, on the other hand, asserts that

Vitamin E refers to alpha-tocopherol alone. Ex. 2001 ¶ 18. It is unnecessary for us to resolve this dispute for purposes of this Decision because we find that Lang’s use of the plural “tocopherols” in Example 3 (and therefore in the gelatin capsule of Example 12) is sufficient to disclose two or more tocopherols mixed in one supplement, as required by the claims.⁸

Regarding claims 13, 17–20, and 24, which depend from claim 12, Petitioner relies on Example 12 and provides a claim chart identifying how the Example discloses the limitations of each claim. Pet. 33–35 (citing Ex. 1009, Example 12, Example 3; Ex. 1024 ¶¶ 93). For claim 23, Petitioner relies on Example 10, which incorporates the beadlet of Example 3, to disclose the additional limitation of taurine. Pet. 37–40 (citing Ex. 1009, Example 10, Example 3; Ex. 1024 ¶ 101). We are persuaded that Petitioner has shown sufficiently that Lang discloses each limitation of those claims for the reasons stated by Petitioner. *See* Pet. 33–35, 37–40 (citing Ex. 1009, Examples 3, 10, 12; Ex. 1024 ¶¶ 93, 101).

Patent Owner argues Lang does not disclose “capsules containing oily carrier materials,” recited in claim 17, because Lang teaches the use of oils within the beadlets. Pet. 15–16. We are not persuaded. Petitioner has shown that the gelatin capsule of Example 12 comprises beadlets that contain vegetable oil/oleoresin. Pet. 34 (citing Ex. 1009, Example 3, Example 12). Thus, the capsules contain oily carrier materials because the

⁸ Consistent with this finding, we also note that claim 4 of Lang recites: “A beadlet according to Claim 1, wherein the antioxidant(s) is/are selected from the group consisting of: . . . , alpha-, beta-, gamma-, delta- and epsilon-tocopherol” Ex. 1009, 25 (claim 4). This claim suggests a beadlet may comprise multiple isoforms of tocopherol.

beadlets—which are within the capsules—contain oily carrier materials. We are not persuaded that the ’384 patent “explicitly disclaims this location,” as asserted by Patent Owner. Prelim. Resp. 15–16 (citing Ex. 1001, 20:62–67⁹). The cited portion of the ’384 patent states, “If desired, such oily carriers can also be formulated to carry microencapsulated beadlets or other preparations, which can contain water-soluble nutrients or any other components that are easier to handle if isolated or otherwise coated in that manner.” Ex. 1001, 20:62–67. It is unclear how this language “explicitly disclaims” the use of an oily carrier in the beadlets, as Patent Owner asserts. At best, this language provides an additional embodiment that may be used “[i]f desired,” and does not rise to the level of an “expression[] of manifest exclusion or restriction, representing a clear disavowal of claim scope.”

Aventis Pharma S.A. v. Hospira, Inc., 675 F.3d 1324, 1330 (Fed. Cir. 2012) (citation omitted). Thus, we find Petitioner has shown sufficiently that Lang discloses a capsule containing oily carrier materials, as required by claim 17.

Regarding claim 21, which requires that “the user has macular degeneration and a lens-related disorder,” Petitioner asserts that Lang discloses this limitation because Lang discloses the use of its dietary supplements to treat macular degeneration and that xanthophylls may be beneficial for improving the health of the macula and clarity of the lens. Pet. 36 (citing Ex. 1001, 2:17–19, 4:16–18, 24:9–1). On this record, we agree with Patent Owner and are not persuaded that Lang discloses the use of the formulation on a user who suffers from both macular degeneration and a lens-related disorder. *See* Prelim. Resp. 17. Thus, at this stage of the

⁹ Patent Owner cites Ex. 1001, 10:62–67, but this appears to be a typo as the quoted language is in column 20 of the ’384 patent.

proceeding, we are not persuaded that Petitioner has shown sufficiently that Lang anticipates claim 21.

3. *Conclusion*

Having considered the arguments and evidence presented by the parties, we find Petitioner has shown a reasonable likelihood that it would prevail on its assertion that claims 12, 13, 17–20, 23, and 24 are unpatentable as anticipated by Lang, but not as to claim 21.

D. Alleged Anticipation over Barker

Petitioner asserts that claims 12, 17, 18, and 20 are unpatentable as anticipated by Barker.¹⁰ Pet. 40–45. Patent Owner opposes Petitioner’s assertion. Prelim. Resp. 17–18. On this record, we determine that Petitioner has established a reasonable likelihood that it would prevail in showing claims 12, 17, 18, and 20 are anticipated by Barker.

1. Barker (Ex. 1011)

Barker relates to “administration of a colorant that is capable of being incorporated into eye tissue and/or causing yellowing of eye tissue[, which] results in an improvement of visual performance.” Ex. 1011, 1:10–12. Barker explains that such colorants, when deposited in the retina, provide a yellow filter that absorbs potentially damaging blue light. *Id.* at 1:12–15. As examples of colorants that can be used, Barker lists carotenoids such as lutein, zeaxanthin, and mesozeaxanthin, and compounds having Vitamin A activity. *Id.* at 1:21–26. Barker also states that the colorants may be used in

¹⁰ On page 40 of its Petition, Petitioner contends that “claims 12, 16–21, and 24” are unpatentable as anticipated by Barker. Pet. 40. However, Petitioner’s arguments on pages 41–45 of its Petition appear to be directed to claims 12, 17, 18, and 20. *See* Pet. 41–45.

combination with an antioxidant such as Vitamin E, Vitamin C, and zinc.
Id. at 1:31–2:5.

An example of a soft gelatin capsule according to the invention is shown in Example 6, reproduced below.

Ingredient	<u>Example 6</u>
	Amount per Capsule
Lutein	6 mg
Zeaxanthin	6 mg
β -Carotene	6 mg
Vitamin E (α -d,l-tocopherol)	200 mg
Vitamin C	500 mg
Zinc (as orotate)	7.5 mg
Lecithin	50 mg
Soy bean oil	200 mg

Example 6 shows a soft gelatin capsule with ingredients including lutein, zeaxanthin, Vitamin E, and soybean oil. *Id.* at 6:2.

2. Analysis

Petitioner asserts that Example 6 of Barker discloses each limitation of claim 12. Pet. 41–44. Regarding the preamble, Petitioner asserts that Barker discloses that colorants such as lutein and zeaxanthin absorb blue light, which can be damaging to the retina. Pet. 41–42 (citing Ex. 1011, 1:10–19, 2:19–25; Ex. 1024 ¶ 115). Regarding the limitation that zeaxanthin is present in the 3R-3R' stereoisomer form and is substantially free of mesozeaxanthin, Petitioner asserts that a person of ordinary skill in the art would understand that Example 6 includes lutein and zeaxanthin, but not mesozeaxanthin, because Barker identifies zeaxanthin and mesozeaxanthin separately as examples of carotenoids. Pet. 42–43 (citing Ex. 1011, 4–5,

Example 6; Ex. 1024 ¶¶ 116–118). Regarding the requirements for lutein, Vitamin C, and mixed tocopherols in the form of a capsule, Petitioner asserts that Barker Example 6 discloses each of these ingredients in a soft gelatin capsule for oral ingestion. Pet. 43–44 (citing Ex. 1011, Example 6; Ex. 1024 ¶¶ 119–122). Specifically, for the mixed tocopherols, Petitioner notes that Barker Example 6 discloses soybean oil, which was known in the art to contain mixed tocopherols. Pet. 43 (citing Ex. 1017, 47). At this stage of the proceeding, we are persuaded that Petitioner has shown sufficiently that Barker anticipates claim 12 for the reasons stated by Petitioner. *See* Pet. 41–44 (citing Ex. 1011, 1:10–19, Example 6; Ex. 1024 ¶¶ 115–122).

Patent Owner argues that Barker does not disclose that zeaxanthin is present in the 3R-3R' stereoisomer form and that Petitioner provides no support for its conclusory assertion that it does. Prelim. Resp. 18. At this stage of the proceeding, we are not persuaded. We agree with Petitioner that Barker distinguishes zeaxanthin (i.e., the 3R-3R' stereoisomer) from mesozeaxanthin (i.e., the 3S-3R' stereoisomer), and we are persuaded on this record that listing only zeaxanthin in the composition of Example 6 would signal to a person of ordinary skill in the art that Example 6 discloses the 3R-3R' stereoisomer that is substantially free of meso-zeaxanthin stereoisomers. *See* Pet. 42; Ex. 1011, 1:15–17, Example 6.

Petitioner asserts that Example 6 of Barker also discloses each limitation of dependent claims 17, 18, and 20. Pet. 44–45 (citing Ex. 1011, Example 6; Ex. 1024 ¶¶ 123–124). Patent Owner does not address those dependent claims beyond its arguments regarding claim 12. At this stage of the proceeding, we are persuaded that Petitioner has shown sufficiently that Barker anticipates claims 17, 28, and 20 for the reasons stated by Petitioner. *Id.*

3. Conclusion

Having considered the arguments and evidence presented by the parties, we find Petitioner has shown a reasonable likelihood that it would prevail on its assertion that claims 12, 17, 18, and 20 are unpatentable as anticipated by Barker.

E. Alleged Obviousness over Lang, Garnett, and Brown

Petitioner asserts that claims 12, 13, 16–21, 23, and 24 are unpatentable as obvious over Lang and Garnett, and that claim 14 is unpatentable as obvious over Lang, Garnett, and Brown. Pet. 45–61. Patent Owner opposes Petitioner’s assertion. Prelim. Resp. 21–23. On this record, we determine that Petitioner has established a reasonable likelihood that it would prevail in showing claims 12, 13, 16–21, 23, and 24 are unpatentable as obvious over Lang and Garnett, and that claim 14 is unpatentable as obvious over Lang, Garnett, and Brown. We incorporate here our earlier findings and discussion regarding the disclosure of Lang.

1. Garnett (Ex. 1012)

Garnett relates to a method “for treating or preventing macular degeneration . . . by administering a preparation of zeaxanthin which contains the 3R-3'R stereoisomer as a sole or heavily dominant stereoisomer.” Ex. 1012, Abstract. Garnett further teaches that zeaxanthin is naturally present in macular cells and “absorbs blue and near-ultraviolet light radiation, thereby protecting retinal cells against phototoxic damage.” *Id.* Thus, according to Garnett, the purified R—R isomer of zeaxanthin can be taken orally as a nutritional supplement by patients suffering from macular degeneration or who want to reduce their risk of macular degeneration. *Id.*

2. *Brown (Ex. 1014)*

Brown is a review article regarding “the role of vitamins, minerals, carotenoids and essential fatty acids in relation to eye health.” Ex. 1014, Abstract. Brown describes that “[t]he omega-3 fatty acids are essential for the normal development of the eye and brain in the infant.” *Id.* at 131. Brown further describes that “[o]mega-3 fatty acids are essential to retinal function at all ages and are found in the receptor outer segments.” *Id.* As further taught by Brown, “[c]onsumption of omega-3 fatty acids has been shown to reduce the incidence of cardiovascular disease, so that they can be considered to have a role of promoting general health with an indirect benefit to the eye.” *Id.*

3. *Analysis*

A patent claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

“[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *KSR*, 550 U.S. at 418. “[I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention

does.” *Id.* Moreover, a person of ordinary skill in the art must have had a reasonable expectation of success of doing so. *PAR Pharm., Inc. v. TWi Pharms., Inc.*, 773 F.3d 1186, 1193 (Fed. Cir. 2014).

Petitioner asserts that claims 12, 13, 17–21, 23, and 24 are unpatentable as obvious over Lang and Garnett. Pet. 47–56. Patent Owner argues that Petitioner has failed to meet its burden because it has failed to show the cited references teach each limitation of claim 12. Prelim. Resp. 22. For the same reasons stated above, Patent Owner asserts Lang does not teach mixed tocopherols, and Garnett does not cure that deficiency. *Id.* Because we find above that Petitioner has shown sufficiently that Lang anticipates claims 12, 13, 17–20, 23, and 24, we find Petitioner has also shown a reasonable likelihood of succeeding on its assertion that Lang and Garnett render those claims obvious, as it is well settled that anticipation is the epitome of obviousness. *See Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1373 (Fed. Cir. 2019) (“[I]t is well settled that a disclosure that anticipates under § 102 also renders the claim invalid under § 103, for anticipation is the epitome of obviousness.”) (internal quotations and citations omitted).

To the extent Petitioner further relies on Garnett’s teaching regarding protecting a user’s eyes against the harmful effect of blue light (Ex. 1012, Abstract) and regarding the highly purified 3R-3R’ stereoisomer (Ex. 1012, 16:43–48), we are persuaded that Garnett also teaches those limitations and that a person of ordinary skill in the art would have been motivated to combine the purified zeaxanthin of Garnett with the Example 12-3 formulation of Lang for the reasons stated by Petitioner. Pet. 51–53 (citing Ex. 1024 ¶¶ 151–154). For example, Petitioner asserts that a person of ordinary skill in the art would have been motivated to combine Garnett and

Lang because both are directed to the same problem of promoting ocular health and preventing/treating ocular disorders using formulations comprising zeaxanthin. *Id.* at 51–52 (citing Ex. 1009, 4:7–18; Ex. 1012, Abstract; Ex. 1024 ¶¶ 151–152).

Claims 14 and 16 depend from claim 12 and further recite “omega-3 fatty acids that are derived from fish oil” and “the daily dosage of zeaxanthin is at least 10 milligrams,” respectively. Ex. 1001, 37:27–29, 38:5–6.

Petitioner asserts that Lang discloses each limitation of claim 12, and that the combination of Lang and Garnett renders claim 12 obvious. Pet. 56. As for the additional limitation of claim 14, Petitioner asserts that Brown teaches that omega-3 fatty acids are an essential nutrient for the eyes and can be found in fish oil. Pet. 56–57 (citing Ex. 1014, 131). Petitioner contends that a person of ordinary skill in the art would have been motivated to incorporate the omega-3 fatty acids of Brown into the zeaxanthin formulation of Lang with a reasonable expectation of success because both teach nutrients that are beneficial to eye health. *Id.* at 57 (citing Ex. 1024 ¶¶ 165–166). Petitioner also asserts that Garnett teaches zeaxanthin formulations comprising a daily dosage of about 0.5 mg to 25 mg of 3R-3R' zeaxanthin. Pet. 58 (citing Ex. 1012, 17:52–57). Petitioner argues that a person of ordinary skill in the art would have been motivated to incorporate at least 10 mg and up to 25 mg of 3R-3R' zeaxanthin as taught by Garnett into the zeaxanthin formulation of Lang to protect a user's eyes from the harmful effect of blue light with a reasonable expectation of success. Pet. 58–59 (citing Ex. 1024 ¶ 173).

At this stage of the proceeding, we are persuaded that Petitioner has shown sufficiently that each limitation of claims 14 and 16 is taught by the combination of Lang, Garnett, and Brown and that a person of ordinary skill

in the art would have had a reason to combine the references with a reasonable expectation of success for the reasons stated by Petitioner. *See* Pet. 56–59 (citing Ex. 1024 ¶¶ 131–132, 163–173).

Regarding claim 21, Petitioner asserts that Lang renders the claim obvious because it “expressly teaches the use of its formulations in users having macular degeneration and a lens-related disorder.” Pet. 60. Patent Owner asserts that Lang does not teach a user who has both disorders and therefore fails to disclose all elements of claim 21. Prelim. Resp. 23. As explained above, we are not persuaded on this record that Lang expressly teaches using the formulation in users having both disorders. But, as Petitioner notes, Lang teaches that the use of xanthophylls like lutein and zeaxanthin “may be beneficial in improving the health of the macula and the clarity of the lens.” *See* Pet. 59 (citing Ex. 1009, 2:17–19). Given this suggestion that lutein and zeaxanthin may be beneficial to both the macula and the lens, we are persuaded at this stage of the proceeding that Petitioner has shown sufficiently that a person of ordinary skill in the art reading Lang would have found it obvious to use the formulation in users with both macular degeneration and a lens-related disorder.

4. Conclusion

Having considered the arguments and evidence presented by the parties, we find Petitioner has shown a reasonable likelihood that it would prevail on its assertion that claims 12–13, 16–21, 23, and 24 are unpatentable as obvious over Lang and Garnett, and its assertion that claim 14 would have been obvious over Lang, Garnett, and Brown.

F. Alleged Obviousness over Lang, Roche, and Brown

Petitioner asserts that claims 12, 13, 17–21, 23, and 24 are unpatentable as obvious over Lang and Roche. Pet. 61–76. Petitioner

further asserts that claim 14 is unpatentable as obvious over Lang, Roche, and Brown. Pet. 72–74. Patent Owner opposes Petitioner’s assertion. Prelim. Resp. 23–24. On this record, we determine that Petitioner has established a reasonable likelihood that it would prevail in showing claims 12, 13, 17–21, 23, and 24 would have been obvious over Lang and Roche, and claim 14 would have been obvious over Lang, Roche, and Brown. We incorporate here our earlier findings and discussion regarding the disclosures of Lang and Brown.

1. Roche (Ex. 1020)

Roche is an FDA premarket notification of a new dietary ingredient, zeaxanthin. Ex. 1020, 1.¹¹ Roche describes that zeaxanthin is a dietary ingredient for dietary supplements, which belongs to a class of carotenoids called xanthophylls. *Id.* at 14. Roche teaches that three isomers of zeaxanthin are normally present in the retina of which the most abundant isomer is “(3R,3’R)-zeaxanthin.” *Id.* Roche also states that “[t]he presently described dietary ingredient contains almost exclusively (3R,3’R)-zeaxanthin, as well as very small amounts of (3R,3’S)-(meso)-zeaxanthin and (3S,3’S)-zeaxanthin.” *Id.* Roche states that the “product will be available as a bulk ingredient in a beadlet formulation containing 5% zeaxanthin (Zeaxanthin 5% TG), for the manufacture of dietary supplements.” *Id.* at 12.

2. Analysis

Petitioner asserts that the combination of Lang and Roche teaches each limitation of claims 12, 13, 17–21, 23, and 24. Pet. 61–76. Because

¹¹ Citations to Roche refer to the page numbers of the document and not the page numbers added to the lower right corner of the page.

we find above that Petitioner has shown sufficiently that Lang anticipates claims 12, 13, 17–20, 23, and 24, we find Petitioner has also shown a reasonable likelihood of succeeding on its assertion that Lang and Roche render those claims obvious as well. *See Realtime Data, LLC*, 912 F.3d at 1373. To the extent Petitioner further relies on Roche’s teaching regarding protecting a user’s eyes against the harmful effect of blue light (Ex. 1020, 23–33) and regarding the highly purified 3R-3R’ stereoisomer (Ex. 1020, 14), we are persuaded that Roche also teaches those limitations and that a person of ordinary skill in the art would have been motivated to combine Roche’s zeaxanthin 5% TG beadlet formulation, which includes very little meso-zeaxanthin with the Example 12-3 formulation of Lang for the reasons stated by Petitioner. Pet. 67–69 (citing Ex. 1024 ¶¶ 205–209). For example, Petitioner asserts that both Lang and Roche are directed to the same problem of “promoting ocular health and preventing/treating ocular disorders, such as macular degeneration, using formulations comprising zeaxanthin.” Pet. 68 (citing Ex. 1009, 4:7–18; Ex. 1020, 17–33; Ex. 1024 ¶ 205).

For the same reasons stated above, we are persuaded that Petitioner has shown sufficiently that Brown teaches the “omega-3 fatty acid” limitation of claim 14 and that a person of ordinary skill in the art would have been motivated to combine the omega-3 fatty acids of Brown with the zeaxanthin formulation of Lang with a reasonable expectation of success. *See supra*.

Finally, Petitioner asserts that claim 21 would have been obvious over Lang and Roche. Pet. 74–75. Patent Owner argues that Lang, Roche, and Brown fail to disclose all elements of claim 21. Prelim. Resp. 24. For the same reasons stated above with respect to Lang and Garnett, we are persuaded that Petitioner has shown sufficiently at this stage of the

proceeding that Lang suggests the use of the formulation in users with both macular degeneration and lens-related disorders. *See supra*.

3. Conclusion

Having considered the arguments and evidence presented by the parties, we find Petitioner has shown a reasonable likelihood that it would prevail on its assertion that claims 12, 13, 17–21, 23, and 24 are unpatentable as obvious over Lang and Roche, and claim 14 would have been unpatentable as obvious over Lang, Roche, and Brown.

III. CONCLUSION

For the foregoing reasons, we conclude that Petitioner has established a reasonable likelihood of prevailing on its assertion that at least one of claims 12–14, 16–21, 23, and 24 of the '384 patent is unpatentable. Accordingly, we institute an *inter partes* review of claims 12–14, 16–21, 23, and 24 on the grounds raised in the Petition.

Our determination in this Decision is not a final determination on the patentability of the challenged claims and, thus, leaves undecided any factual issues necessary to determine whether sufficient evidence supports Petitioner's contentions by a preponderance of the evidence in the final written decision. *See TriVascular, Inc. v. Samuels*, 812 F.3d 1056, 1068 (Fed. Cir. 2016) (noting that “there is a significant difference between a petitioner's burden to establish a ‘reasonable likelihood of success’ at institution, and actually proving invalidity by a preponderance of the evidence at trial”) (quoting 35 U.S.C. § 314(a) and comparing § 316(e)).

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 12–14, 16–21, 23, and 24 of U.S. Patent No. 10,307,384 B2 is instituted with respect to the grounds set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial, which will commence on the entry date of this decision.

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